PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton – 50 ml, 250 ml & 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10 mg/ml

3. PACKAGE SIZE

50ml
250ml
500ml

4. TARGET SPECIES

Cattle, sheep and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: 49 days.
Milk: Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Sheep:
Meat and offal: 42 days.
Milk: Do not use in lactating sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

Pigs:
Meat and offal: 28 days.

8. EXPIRY DATE

Exp.
Once opened use within 28 days.
Once broached use by _____.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.
The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 50146/4002

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label – 50 ml, 250 ml & 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10 mg/ml

3. TARGET SPECIES

Cattle, sheep and pigs.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal: 49 days.
Milk: Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Sheep:
Meat and offal: 42 days.
Milk: Do not use in lactating sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

Pigs:
Meat and offal: 28 days.

6. EXPIRY DATE

Exp.
Once opened use within 28 days.
Once broached use by _____.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

9. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bimectin 10 mg/ml solution for injection for cattle, sheep and pigs

2. Composition

Each ml contains:

Active substance:
Ivermectin 10 mg

A clear, colourless, slightly viscous, non-aqueous sterile solution.

3. Target species

Cattle, sheep and pigs.

4. Indications for use

For the effective treatment and control of the following harmful parasites of cattle, sheep and pigs:

Cattle:
Gastrointestinal roundworms (adult and fourth stage larvae): *Ostertagia* spp (including inhibited *O. ostertagi*), *Haemonochus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp, *Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult), *N. spathiger* (adult). *Trichuris* spp. (adult)
Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus.*
Eyeworms (adult): *Thelazia* spp.
Warbles (parasitic stages): *Hypoderma bovis* and *H. lineatum.*
Mange mites: *Psoroptes bovis, Sarcoptes scabiei* var. *bovis.*
Sucking lice: *Linognathus vituli, Haematopinus eurysternus* and *Solenopotes capillatus.*

May also be used as an aid in the control of the mange mite *Chorioptes bovis* and biting lice *Damalinia bovis*, but complete elimination may not occur.

Persistent activity
Treatment at the recommended dose rate can control re-infection with *Haemonchus placei* and *Cooperia* spp. acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesphagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of the veterinary medicinal product for grazing animals, it is recommended that calves which are set stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set stocked in the programme and that no untreated cattle are added to the pasture. Treated calves should always be monitored according to good husbandry practices.

Sheep:
Gastrointestinal Roundworms (adult and fourth stage larvae): *Ostertagia circumcincta* (including inhibited fourth stage larvae), *O. trifurcata, Haemonchus contortus* (including inhibited fourth stage larvae)*, Trichostrongylus colubriformis, Cooperia curticei, Oesphagostomum columbianum, Nematodirus filicollis, Chabertia ovina, Trichostrongylus. axei* (adult), *T. vitrinus* (adult), *Oesphagostomum venulosum* (adult), *Trichuris ovis* (adult).
Lungworms (adult and fourth stage): *Dictyocaulus filaria, Protostrongylus rufescens* (adult).
Nasal bots (adult immature): *Oestrus ovis* (includes somatic larval stages).

Pigs:
Gastrointestinal roundworms (adult and fourth stage larvae): *Ascaris suum, Hyostrongylus rubidus, Oesophagostomum* spp. and adult and somatic larval stages of *Strongyloides ransomi.*
Lungworms: *Metastrongylus* spp. (adult)
Lice: *Haematopinus suis.*
Mites: *Sarcoptes scabiei* var. *suis.*

5. Contraindications

Do not use in cases of hypersensitivity to the active ingredient or to any of the excipients.
This veterinary medicinal product is not for intravenous or intramuscular use.

6. Special warnings

Special warnings:
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic

belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Teladorsagia circumcincta* in sheep and *Ostertagia ostertagi* in cattle. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Take care to avoid self-administration: the veterinary medicinal product may cause local irritation and/or pain at the site of injection.
Direct contact of the veterinary medicinal product with the skin should be kept to a minimum.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.

Other precautions:
When using the 250 ml and 500 ml pack sizes, use only automatic syringe equipment. For the 50 ml pack size, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw off needle is recommended to avoid excessive broaching of the stopper.

The veterinary medicinal product has been formulated specifically for use in cattle, sheep and pigs. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Pregnancy:
The veterinary medicinal product can be used in beef cows, sheep and pigs during pregnancy.

Lactation:
Do not use in dairy cows or sheep producing milk for human consumption.
Do not use in non-lactating dairy cows or sheep within 60 days of calving/lambing.
The veterinary medicinal product can be used in sows during lactation.

Fertility:
Fertility is not affected by administration of the veterinary medicinal product.

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

Overdose:

Cattle
Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

Sheep
At dose levels up to 4 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression. No signs of systemic toxicity were observed in sheep treated with the veterinary medicinal product at up to 3 times the recommended dose rate, soft tissue swellings at the injection site were observed.

Pigs
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

Major incompatibilities:
Do not mix with other veterinary medicinal products.

7. Adverse events

Cattle, Sheep and Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site pain[1,2] Injection site swelling[3]

[1] Mild and transient following subcutaneous administration.
[2] In sheep: sometimes intense.
[3] In cattle only.

All these reactions disappeared without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Subcutaneous use.
The veterinary medicinal product should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and over the neck in sheep. At the recommended dosage level of 300 mcg ivermectin per kg of bodyweight, the veterinary medicinal product should be given only subcutaneously in the neck of pigs.

9. Advice on correct administration

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep and 33 kg of bodyweight of pigs. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals.

Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw the product from the container. Massage the injection site after administration of the veterinary medicinal product.

In young pigs, especially those below 16 kg for which less than 0.5 ml of the veterinary medicinal product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

In young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs the use of a syringe with can deliver as little as 0.1 ml is recommended.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

The use of suitably calibrated measuring equipment is recommended.

If animals are to be treated collectively rather than individually they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over- dosing.

10. Withdrawal periods

Cattle:
Meat and offal: 49 days.
Milk: Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Sheep:
Meat and offal: 42 days.
Milk: Do not use in lactating sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

Pigs:
Meat and offal: 28 days.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50146/4002

Pack sizes:
Cardboard box with 1 x 50 ml bottle.
Cardboard box with 1 x 250 ml bottle.
Cardboard box with 1 x 500 ml bottle.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

Local representatives and contact details to report suspected adverse reactions:
Cross Vetpharm Group UK Limited (Trading as Bimeda)
Unit 2, Bryn Cefni Industrial Park
Llangefni, LL77 7XA
United Kingdom
Tel: 01248 725 400

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-VPS

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic endectocides.

Gavin Hall

Approved 01 May 2025